K093551

DEC 2 4 2009

510(k) Summary

Contact:	Sally Thorsen SpineMedica, LLC 811 Livingston Court, Suite B Marietta GA 30067 (678) 384-6727 Fax 678-384-6741 sthorsen@spinemedica.com
Device Trade Name:	Paradís Vaso Shield™
Manufacturer:	SpineMedica, LLC 811 Livingstone Court, Suite B Marietta, GA 30067
Classification:	21 CFR 870.3470, Vessel Guard
Class:	II
Product Code:	OMR

Indications For Use:

The SpineMedica *Paradís Vaso Shield*™ is indicated as a cover for vessels following anterior vertebral surgery.

Device Description:

The SpineMedica *Paradís Vaso Shield*™ is a flexible sheet of 30 Wt.% polyvinyl alcohol (PVA) material with dimensions of 60 ±6 mm X 100 ±10 mm and a thickness of 1.0 ±0.2 mm. The corners of the sheet are rounded. There are no holes or perforations. There are no markings on either side of the sheet, raised (embossed) or printed. The sheet is provided sterile and hydrated in saline solution.

Predicate Device(s):

The SpineMedica *Paradís Vaso Shield*™ was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and/or materials.

Performance Standards:

Testing performed indicates the SpineMedica *Paradís Vaso Shield*™ is substantially equivalent to predicate devices.

Summary of Safety and Effectiveness:

As part of the Special 510(k) submission, additional shelf life expiration date information is submitted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 2 4 2009

SpineMedica, LLC
c/o Sally Thorsen
Director, Quality and Regulatory Affairs
811 Livingston Court, Suite B
Marietta, GA 30067

Re: K093551
Trade Name: SpineMedica Paradís Vaso Shield™
Regulation Number: 870.3470
Regulation Name: Intracardiac patch or pledget
Regulatory Class: II
Product Code: OMR
Dated: November 13, 2009
Received: November 17, 2009

Dear Ms. Thorsen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device with a 12 month shelf life, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling and any promotional materials:

> The safety and effectiveness of this device for reducing the incidence, severity, and extent of post-operative adhesion formation have not been established.

Furthermore, the indication for use as a cover for vessels following anterior vertebral surgery must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093551

Indications for Use

510(k) Number (if known):

Device Name: **SpineMedica Paradís Vaso Shield™**

The SpineMedica *Paradís Vaso Shield*™ is indicated as a cover for vessels following anterior vertebral surgery.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K093551